

JUN 10 2004

TECH CENTER 1600/2900

BOSE McKINNEY & EVANS LLP

CUSTOMER NUMBER 25267

2700 First Indiana Plaza  
135 North Pennsylvania Street  
Indianapolis, Indiana 46204

PATENT APPLICATION

*IN THE UNITED STATES PATENT AND TRADEMARK OFFICE*

Group: 1615

Atty. Docket: 12330-0003

Applicants: Zimmerman

Title: MALE CONTRACEPTIVE

Serial No.: 10/022,671

Filed: 12/17/2001

Examiner: Oh, Simon J.

Certificate Under 37 CFR 1.10

Express Mail Label No.: \_\_\_\_\_

Date of Deposit: \_\_\_\_\_

I hereby certify that this paper or fee is being deposited with the United States Postal Service's "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Patent Application, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450

\_\_\_\_\_  
Typed or Printed Name of Person Mailing Paper or Fee

\_\_\_\_\_  
Signature of Person Mailing Paper or Fee

DECLARATION OF RONALD ZIMMERMAN, Ph.D.

NOW COMES the applicant, Ronald E. Zimmerman, Ph.D., pursuant to the provisions of 37 C.F.R. 1.132, and states as follows:

1. I am Ronald E. Zimmerman, the applicant in the above identified patent application. My education is as follows: B.S., Indiana State University, 1966; Ph.D., Indiana State University, 1968.

2. I am a named inventor in at least the following United States Patents dealing with the subject of contraception: U.S. Patent No. 4,264,577, U.S. Patent No. 4,264,578, U.S. Patent No. 4,264,575, U.S. Patent No. 4,264,576.

3. In addition, I am an inventor in the following additional United States patents: 5,272,076; 4,493,699 and 4,469,671.

4. I have worked in and around the field of contraception since at least as early as 1978, and thus am to be considered as one of at least ordinary skill in the art.

5. I have reviewed the Examiner's rejection of each of the presently pending claims 1-19, and the Examiner's comments in that regard. I do not agree with the Examiner's comments, as explained herein.


6. Essentially, the Examiner has equated (a) the teachings of my prior invention as set forth in U.S. Patent No. 4,264,577 with the inventions set forth in presently pending claims 1-19. The Examiner's conclusion of "inherency" and of *prima facie* obviousness are erroneous.

7. Specifically, U.S. Patent No. 4,264,577 teaches the administration of certain compounds *in utero*, and thus, within the female. The '577 Patent does comment that in the prior art, certain other (and very different) compounds (i.e., estrogen/progestin or progestin alone) had been used by administration *in vivo* within the female. However, there is no teaching or suggestion in the '577 Patent of any utilization of such prior art estrogen/progestin or progestin compounds in the male, nor is there any teaching or suggestion that the '577 prior art could or should be modified with any reasonable likelihood of success for changing the taught *in utero* administration in the female to an *in vivo* administration within the male, whether orally, transdermally, subcutaneously, or otherwise. The '577 patent teaches inventions using a class of alkyl or alkenyl sulfate salts *in utero* in the females. However, there is no teaching or suggestion in the '577 patent of any utilization of the sulfate salt compounds in the male. Nor is there any teaching or suggestion in the '577 patent teachings that sulfate salts could or should be modified with any reasonable likelihood of success for changing the taught *in utero* administration in the female to an *in vivo* administration within the male, whether orally, transdermally, subcutaneously, or otherwise. Moreover, there is no teaching or suggestion in the cited '577 prior art that the subject sulfate


salts would be useful as an oral contraceptive. In fact, in tests conducted by me these compounds were administered orally to females and there was no contraceptive effect.

8. One reason for the lack of any such teaching or suggestion is the vast differences in environmental conditions between (a) the vagina or uterus of the female, and (b) the stomach, intestines, testes, and bloodstream of the male.

9. Accordingly, and in summary, there is no teaching or suggestion in the '577 Patent of the applicant's invention as set forth in presently pending claims 1-19.

  
\_\_\_\_\_  
Ronald E. Zimmerman, Ph.D.

The above indicated Declarant does hereby acknowledge that willful, false statements and the like are punishable by fine or imprisonment, or both. (18 U.S.C. 1001), and may jeopardize the validity of the application or any patent ensuing thereon. The above statements that are made of the Declarant's own knowledge are true, and all statements made and information are believed to be true.

  
\_\_\_\_\_  
Ronald E. Zimmerman, Ph.D.

\$26169